# Memorandum

To: Panel Members Date: September 26, 2001

From: Diana Torres, Manager File: Alliance-II.130agr

Peter DeMauro, General Counsel

Subject: One-Step Agreement for Alliance Pharmaceutical Corp.

(www.allp.com)

## **CONTRACTOR:**

• Training Project Profile: Retraining: companies w/out-of-state competition

• Legislative Priorities: Promotion of California's Manufacturing Workforce

Moving to a High Performance Workplace

• Type of Industry: Manufacturing Biotechnology/Pharmaceutical

• Repeat Contractor: Yes

• Contractor's Full Time Employees:

Company Wide: 175

In California: 175

• Fringe Benefits: Yes

• Union Representation: No

• Name and Local Number of Union

representing workers to be Trained: N/A

## **CONTRACT:**

• Program Costs: \$155,610

• Substantial Contribution: \$0

• Total ETP Funding: \$155,610

• In-Kind Contribution: \$400,000

Reimbursement Method: Fixed-Fee

County(ies) Served: San Diego

• Duration of Agreement: 24 Months

## **TRAINING PLAN:**

• Average Cost Trainee: New Hire: \$0 Retrainee: \$1,245

Type(s) of Training: Business Skills, Continuous Improvement, Computer

Skills

• Number to be retained: New Hire: 0 Retrainee: 125

• Range of hours: 40 - 180

• Range of hourly wages: \$10.82 to \$52.88

Prevalent hourly wage: \$30.29Weighted average hourly wage: \$30.29

• Health benefits used to meet ETP

minimum wage: No

## **SUBCONTRACTORS:**

Quest Consulting & Training, Inc. in Pacific Palisades, California, - \$13,500 for Project Administration

Quest Consulting & Training, Inc. in Pacific Palisades, California, - \$41,548 for Class/Lab Training

Bekins Consulting Group in San Diego, California, - \$5,875 for Class/Lab Training

H.R. Tactics in San Diego, California, - \$32,000 for Class/Lab Training

Vortex Data Systems in San Diego, California, - \$107,291 for Class/Lab Training

Technology Integration Group in San Diego, California, - amount not yet determined for Class/Lab Training

## THIRD PARTY SERVICES:

Quest Consulting & Training, Inc. assisted in the design of the training program and completion of the application. Amount reimbursed for these services was \$15,000, which applicant states is based on a flat rate.

## **PRIOR PROJECTS:**

The following are completed project statistics for ETP Agreements with this Contractor within the last five years:

Agreement No.	Location (City)	Term	Agreement Amount	Amount Earned	% Earned
ET6-0152	San Diego	03/06/96 - 03/05/98	\$129,224	\$82,581	64%

Contractor's representatives report that Alliance Pharmaceutical went through a reorganization during the previous ETP Agreement that resulted in some voluntary quits. As a result, the company was unable to train the number of people planned. Additionally, some trainees that completed their class/lab training were unable to complete their Structured, On-Site Training (SOST) and the company did not earn reimbursement for these trainees. Under this proposed Agreement there is no SOST component, and company representatives state that the reorganization is complete and the workforce now stable.

### **NARRATIVE:**

Alliance Pharmaceutical Corp. (Alliance) researches, develops, and manufactures therapeutic and diagnostic products for human use. Alliance develops drug products based on a class of compounds known as perfluorochemicals (PFC's), which are intended primarily for use during acute care critical situations including surgical, cardiology and respiratory indications. These products include diagnostic imaging agents, oxygen delivery agents and agents used to treat respiratory distress. Alliance also manufactures drug products that are used in preclinical and clinical trials. Founded in 1987, the company employs 175 full-time people at its three facilities, which include manufacturing, research and development, and corporate offices, all located in San Diego.

Alliance Pharmaceutical produces products that are sold out-of-state and is eligible for Panel funding under the out-of-state competition provisions outlined in Title 22, California Code of Regulations, Section 4416(b) for industrially classified manufacturers.

Since the last ETP Agreement, Alliance has been involved in research and development of three main products, each of which has gone through preclinical testing and two phases of clinical trials. The company has now completed the necessary Phase III clinical trials on one drug and has applied to the U.S. Food and Drug Administration (FDA) for marketing approval of this product. Upon approval from the FDA, (anticipated by early 2002) the focus of the company will dramatically shift from research and development, to manufacturing and marketing. Alliance's manufacturing staff must then move quickly from manufacturing drugs for preclinical and clinical use to manufacturing drugs for direct patient use. This will require the company to go from manufacturing 18,000 units per year to manufacturing150,000 units the first year after approval with increases projected in each subsequent year.

This diversification of Alliance's products and services requires employees to have more sophisticated levels of understanding and compliance with Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP), and be able to maintain 100 percent reliability in the sterile manufacturing process. Employees will now require high levels of skill in Documentation Management, Clinical Research Practices, Design of Experiments, Product Familiarization, and Standard Operating Procedures. This Continuous Improvement training is critical so that employees are better equipped with the clinical research and manufacturing skills to address the needs of the company's change in business focus and to better manage their processes.

Additionally, Alliance's marketing staff will begin an international campaign to bring worldwide awareness to Alliance's products. With the new company focus on worldwide marketing, comes new job responsibilities for some engineers, scientists, managers and directors. These employees will need advanced training in Computer Skills such as database administration and website development to

develop proper skill sets that will be used to support worldwide product sales and marketing. In the biotechnology and pharmaceutical industries, computer technology is constantly changing and evolving. By 2005, the company will be mandated to submit entire dossiers electronically to the FDA. Employees must remain competent in the latest systems. Therefore, some Clinical Research Staff, Manufacturing Staff and Support Staff will receive training in intermediate and advanced Microsoft Word applications, Microsoft Certified Technical Courses, Novell Network Development and Visual Basic.

In addition to the company's diversification of products and services, the FDA has also increased its scrutiny of Alliance's quality, manufacturing and clinical research systems. Other international regulatory agencies have also increased their quality standards for regulatory approval. At the same time, as the company enters its new business phase to manufacture drugs for patient use, Alliance projects that increased expectations of patients will drive the company to redefine and upgrade the definition of quality for its workforce. Alliance recognizes that it must take the company to the next level of a High Performance Workplace and that training in new skills is critical.

To successfully support this new work environment and ingrain the principles of high quality, employees must become multi-skilled to improve the quality and safety of current products, and must prepare for the introduction of new products. Alliance must offer higher quality products while maintaining a competitive cost structure. Consequently, the company must develop cost-effective manufacturing methods, enhance teamwork and involve Research and Development Staff, Manufacturing Staff, and Support Staff in decision making, problem solving and implementing improvements. The Business Skills classes proposed here, Behavioral Styles, Conflict Management, Leadership Essentials, Managing Change, Performance Management, Presentation Skills, Problem Solving and Decision Making, and Technical Writing will provide the skills necessary for the employees to recognize and achieve the company's quality goals and improve the skill level, productivity, and decision-making capabilities of the workforce in a high performance environment. Employees will also learn how to better manage the dramatic changes occurring in the company and industry.

With the assistance from ETP, Alliance Pharmaceutical will be able to provide its employees with the skills necessary to successfully diversify its products and services and continue its transition to a high performance workplace. Under this proposal 125 full-time employees will receive from 40 to 180 class/lab training hours in a menu style curriculum based on the needs of each trainee. There is no Structured, On-Site Training or Computer-Based Training in this proposal and class/lab training will be provided by outside vendors and in-house instructors. Partial project administration will be provided by vendor.

#### Supplemental Nature of Training

The Contractor has certified in writing that this proposed training in Business Skills, Continuous Improvement, and Computer Skills is supplemental to training that the company provides in the normal course of its business, and is also different training from what was provided in the prior ETP Agreement (1996/97). In the prior ETP Agreement, the company's workforce needed training to help the employees begin their transformation to a high performance workplace. The training that was provided was generic in nature and the company's focus at that time was primarily research and development.

The need for training in this proposed Agreement is different from the prior Agreement. As stated earlier, Alliance is now diversifying its products and services from research and development, to manufacturing and marketing. Although Alliance may offer some classes that appear similar to what was offered before, the training is different. Since it has been over three years since training ended in the prior ETP

Agreement, and due to the aforementioned changes the company has experienced, the course content of the proposed training curricula been redesigned and customized to meet the current business needs at the company. For example, GMP training was offered previously, but this course has been updated to reflect the company's new focus on manufacturing drugs for patient use.

The proposed training also differs from Alliance's current on-going training program. Alliance's annual training budget is approximately \$30,000 per year and the typical training classes offered consist of new employee orientation, on-the-job procedural training, supervisory skills, computer skills in the area of upgrades and equipment changes, company policies and procedures, employment law, laboratory animal facility procedures and laboratory technician training. All of this training is part of the company's ongoing training plan and will continue at the company's expense, and is not included in the ETP-funded portion of the proposed Agreement.

On-going training at Alliance, outside of ETP training, is usually sporadic, informal and is done mostly in one half hour increments on a "just-in-time" philosophy, and is also of a generic nature. The proposed training in Business Skills, Continuous Improvement and Computer Skills is supplemental training because it is formal training, was developed out of an extensive needs assessment, is "Alliance-specific" in content, and ETP training will be provided in two to eight hour increments. Finally, the company has certified that in the absence of ETP funding, the company could only provide a limited amount of training for smaller groups.

#### **In-Kind Contribution**

Alliance Pharmaceutical Corp. will invest approximately \$400,000 for ETP training related costs. This amount includes \$80,000 for project development costs, \$20,000 in training material costs and wages paid to trainees during ETP training of approximately \$300,000.

#### **COMMENTS:**

#### Senior Policy Managers/Executive Level

Only frontline workers and frontline supervisors and managers are included in this project; no senior policy managers or executive level employees are included.

#### Advanced Degrees

Company representatives state that no occupations/trainees in this proposal are required to have an advanced degree (masters degree or above) for their jobs.

#### **PROPOSED ACTION:**

Staff recommends that the Panel approve this Agreement if funds are available and the project meets Panel priorities. This project will help Alliance Pharmaceutical Corp. remain competitive, provide the necessary skills to its employees to meet the needs of diversifying its products and services, and will enable the company to remain viable in the California economy.

Training Data									(c) Payment Schedule				
1 Job #	2 Occupations	3  Type of Training	4 No. Retain	5 (a) Cls/Lab Video- conf. Hours	6 CBT Hours	7 (b) SOST Hours	8 Cost Per Trainee	9 Total SOST Trainer Hrs.	Hrs. to Enroll/ Pay 1 Enroll	11 Pay 2 Compl	Pay 3 Hired	Pay 4 After 90 Days	14 (d) Wage After Reten- tion
	Admin. Asst., Biostatistician, Coordinator, Director, Doc.Processor, Drafter, Operator, Specialist, Technician, Technologist, Manager	Direct-Employer, Retrainees MENU: Trainees will receive one or more of the following Business Skills Continuous Improvement Computer Skills	25	40 40			\$520		8 \$ 130.00	\$ 260.00	\$ -	- \$ 130.00	\$10.82 - \$52.88
	Admin. Asst., Associate, Auditor, Biostatistician, Coordinator, Director, Doc. Processor, Drafter, Operator, Programmer, Scientist, Specialist, Technician, Technologist, Supervisor, Manager	Direct-Employer, Retrainees MENU: Trainees will receive one or more of	35	60			\$780		8 \$ 195.00	\$ 390.00	\$ -	- \$ 195.00	\$10.82 - \$52.88

60

687

the following Business Skills

Computer Skills

Continuous Improvement

<sup>(</sup>a)Advanced Technology must be provided as class/lab.

<sup>(</sup>b) Figures for calculation purpose only.

<sup>(</sup>c)For Welfare to Work: Pay 2=50% Completion hrs. Pay 3=100% Completion hrs.

<sup>(</sup>d)Wages by occupation on Comment Page.

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	Training Data								(c) Payment Schedule				
1 Job #	2 Occupations	3  Type of Training	4 No. Retain	5 (a) Cls/Lab Video- conf. Hours	6 CBT Hours	7 (b) SOST Hours	8 Cost Per Trainee	9 Total SOST Trainer Hrs.	Hrs. to Enroll/ Pay 1 Enroll	Pay 2 Compl	12 Pay 3 Hired	Pay 4 After 90 Days	14 (d) Wage After Reten- tion
3 687	Biostatistician, Coordinator, Director, Specialist, Technician, Research Assistant, Scientist, Manager	Direct-Employer, Retrainees MENU: Trainees will receive one or more of the following Business Skills Continuous Improvement Computer Skills	9	80 80			\$1,040		8 \$ 260.00	\$ 520.00	\$ -	\$ 260.00	\$14.42 - \$52.88
4 687	Chemist, Coordinator, Engineer, Technician, Drafter, Research Associate, Scientist	Direct-Employer, Retrainees MENU: Trainees will receive one or more of the following Business Skills Continuous Improvement Computer Skills	17	110 110			\$1,430		8 \$ 357.50	\$ 715.00	\$ -	\$ 357.50	\$12.50 - \$38.46

<sup>(</sup>a)Advanced Technology must be provided as class/lab.

<sup>(</sup>b) Figures for calculation purpose only.

<sup>(</sup>c)For Welfare to Work: Pay 2=50% Completion hrs. Pay 3=100% Completion hrs.

<sup>(</sup>d)Wages by occupation on Comment Page.

Training Data									(c) Payn	nent Sch	edule		
1 Job#	2 Occupations	3  Type of Training	4 No. Retain	5 (a) Cls/Lab Video- conf. Hours	6 CBT Hours	7 (b) SOST Hours	8 Cost Per Trainee	9 Total SOST Trainer Hrs.	Hrs. to Enroll/ Pay 1 Enroll	Pay 2 Compl	12 Pay 3 Hired	Pay 4 After 90 Days	14 (d) Wage After Reten- tion
5 687	Director, Specialist, Research Associate, Scientist, Manager	Direct-Employer, Retrainees MENU: Trainees will receive one or more of the following: Business Skills Continuous Improvement Computer Skills	11	140 140			\$1,820		8 \$ 455.00	\$ 910.00	\$ -	\$ 455.00	\$14.42 - \$52.88
6	Coordinator, Director, Drafter, Engineer, Operator, Scientist, Specialist, Technician, Technical Writer	Direct-Employer, Retrainees MENU: Trainees will receive one or more of the following Business Skills Continuous Improvement Computer Skills	10	150 150			\$1,950		8 \$ 487.50	\$ 975.00	\$ -	\$ 487.50	\$14.42 - \$52.88
7 687	Administrator, Director, Engineer, Scientist, Supervisor, Manager	Direct-Employer, Retrainees MENU: Trainees will receive one or more of the following Business Skills Continuous Improvement Computer Skills	18	180 180			\$2,340		8 \$ 585.00	\$ 1,170.00	\$ -	\$ 585.00	\$14.42 - \$52.88

<sup>(</sup>a)Advanced Technology must be provided as class/lab.

<sup>(</sup>b) Figures for calculation purpose only.

<sup>(</sup>c)For Welfare to Work: Pay 2=50% Completion hrs. Pay 3=100% Completion hrs.

<sup>(</sup>d)Wages by occupation on Comment Page.

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	Training Data									(c) Payn	nent Sch	edule	
1	2	3	4	5	6	7	8	9	10	11	12	13	14
				(a)									<b>(d)</b>
				Cls/Lab				Total					Wage
				Video-		<b>(b)</b>	Cost	SOST	Hrs. to	Pay		Pay 4	After
			No.	conf.	CBT	SOST	Per	Trainer	Enroll/ Pay	2	Pay 3	After 90	Reten-
Job#	Occupations	Type of Training	Retain	Hours	Hours	Hours	Trainee	Hrs.	1 Enroll	Compl	Hired	Days	tion

Contract '	<b>Totals</b>
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Program Cost	\$155,610	<b>Total to be Retained</b>	125
Substantial Contribution (%) (-)	\$0		
Multiple-Empl. Support (%) (+)	\$0		
TOTAL ETP Funding (=)	\$155,610		

<sup>(</sup>a)Advanced Technology must be provided as class/lab.

<sup>(</sup>b) Figures for calculation purpose only.

<sup>(</sup>c)For Welfare to Work: Pay 2=50% Completion hrs. Pay 3=100% Completion hrs.

<sup>(</sup>d)Wages by occupation on Comment Page.

Exhibit A

Turnover Rate	% of Mgrs. & Sups. to be trained	Health Benefits Inc. in Wage?	
15.0%	N/A	NO	

Location of training: Training will be conducted at three company sites in San Diego or at Subcontractor premises in San diego during work hours.

<u>Ratios:</u> The ratio of trainers to trainees for class/lab shall not exceed 1:20 for retrainees.

If Health Benefits is "YES", please explain: N/A

#### Other notes:

# (d) Wages by occupation after retention:

Occupations	Wage Range
Administrator	\$19.23 - \$38.46
Biostatistician	\$19.23 - \$38.46
Coordinator	\$19.23 - \$38.46
Administrative Asstistant	\$12.50 - \$18.27
Technologist	\$10.82 - \$15.38
Drafter	\$14.42 - \$28.85
Document Processor	\$14.42 - \$21.63
Specialist	\$14.42 - \$28.85
Operator	\$10.82 - \$21.63
Technician	\$14.42 - \$38.46
Director	\$28.85 - \$52.88
Research Assistant	\$14.42 - \$21.63
Research Associate	\$19.23 - \$52.88
Programmer	\$19.23 - \$38.46
Auditor	\$28.85 - \$52.88
Scientist	\$12.50 - \$52.88
Chemist	\$19.23 - \$38.46
Engineer	\$14.42 - \$38.46
Technical Writer	\$14.42 - \$28.85
Supervisor	\$19.23 - \$38.46
Manager	\$19.23 - \$52.88